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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,316

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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT

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1651

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,316	Applicant(s) HIGASHIYAMA ET AL.	
	Examiner SHERIDAN R. MACAULEY	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/13/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A response and amendment were received and entered. New claims 9-11 are added. Claims 1-11 are pending and examined on the merits in this office action.

Claim Objections

Claim objections are withdrawn due to amendment.

Claim Rejections - 35 USC § 112

1. Rejections under 35 USC 112 have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 and 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP3163127 (see English abstract) in view of Yamanka (US 3,882,635). Claim 1 recites a process for producing astaxanthin-containing lipids which comprises culturing green alga with an organic nitrogen source being used in a medium at an AN/TN ratio of 65% or less, preferably 43% or less, more preferably 35% or less, to obtain algal bodies in which astaxanthin-containing lipids have been stored. Claim 3 recites the process according to claim 1, wherein the organic nitrogen source is at least one organic nitrogen source selected from the group consisting of corn steep liquor, soya bean powder, peptone, tripeptone, and polypeptone. Claim 4 recites the process according to claim 1, wherein the organic nitrogen source is used at least 0.1 g/L. Claim 5 recites the process according to claim 4, wherein culture is performed in a reactor under the dark condition. Claim 6 recites the process according to claim 5, wherein culture is performed under aerobic conditions. Claim 7 recites the process according to claim 4, wherein culture is performed in a reactor under the light condition or in an outdoor,

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closed system. Claim 8 recites the process according to claim 5, wherein astaxanthin is stored at a concentration of at least 10 mg/L of the culture solution or at least 40 pg/cell.

Claims 9 and 10 recite that the alga is of the genus *Haematococcus*, specifically *Haematococcus pluvalis* or *Heamatococcus lacustris*. Claim 11 recites that the cultivation is in a liquid culture.

6. JP3163127 teaches a process for producing astaxanthin that comprises culturing green alga, specifically *Haematococcus pluvalis*, with an organic nitrogen source to obtain algal bodies in which the astaxanthin, which would be contained in lipids, has been stored (see English abstract). The reference teaches that organic nitrogen used in the process is yeast extract at a concentration of 2 g/L (see English abstract). The reference teaches that culture is performed in a liquid culture, under aerobic conditions and may be performed in a reactor under light or dark conditions (see English abstract). The method of the reference does not teach the specific AN/TN ratio of the organic nitrogen source, and does not teach the use of the nitrogen sources recited in the claims.

7. Yamanaka teaches a process for producing green algae wherein the alga is cultured with an organic nitrogen source, wherein the organic nitrogen source comprises peptone (col. 3, example 1).

8. At the time of the invention, a process for producing astaxanthin comprising nearly all of the claimed steps was known, as taught by JP3163127. It was also known that green algae could be grown using organic nitrogen sources, as taught by JP3163127 and Yamanaka. One of ordinary skill in the art would have been motivated

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to alter the organic nitrogen sources to use a source with the claimed AN/TN range, such as peptone, because Yamanaka teaches that green alga can be grown with a variety of nitrogen sources including peptone (col. 2. lines 61-col. 3, line 2). One would therefore have achieved the claimed ratio in the course of routine optimization. One would have had a reasonable expectation of success in combining the teachings discussed above to arrive at the claimed method because green alga, particularly those producing astaxanthin, were known to be compatible with organic nitrogen at the time of the invention, as taught by JP3163127 and Yamanaka. It would therefore have been obvious to combine the teachings of the prior art to arrive at the claimed invention.

9. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP3163127 (see English abstract) in view of Yamanka (US 3,882,635) as applied to claims 1 and 3-11 above, and further in view of Tanaka (WO 02/077105; see English translation US 2004/0091524 A1). Claims 1 and 3-11 are discussed above. Claim 2 recites the process according to claim 1, further including the steps of extracting the astaxanthin-containing lipids from the algal bodies and optionally purifying the extracted lipids.

10. JP3163127 teaches a process for producing astaxanthin that comprises culturing green alga with an organic nitrogen source to obtain algal bodies in which the astaxanthin, which would be contained in lipids, has been stored (see English abstract). The reference teaches that organic nitrogen used in the process is yeast extract at a concentration of 2 g/L (see English abstract). The reference teaches that culture is

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performed under aerobic conditions and may be performed in a reactor under light or dark conditions (see English abstract). The method of the reference does not teach the specific AN/TN ratio of the organic nitrogen source, and does not teach the use of the nitrogen sources recited in the claims.

11. Yamanaka teaches a process for producing green algae wherein the alga is cultured with an organic nitrogen source, wherein the organic nitrogen source comprises peptone (col. 3, example 1).

12. At the time of the invention, it would have been obvious to combine JP3163127 and Yamanaka to arrive at nearly every element of the claimed invention, as discussed above. Neither reference, however, discusses the extraction of astaxanthin-containing lipids from the algal bodies.

13. Tanaka teaches a method of extracting a lipid containing astaxanthin from ruptured algae (p. 1, par. 2).

14. At the time of the invention, a method for the production of astaxanthin from green alga comprising nearly all of the claimed elements was known, as taught by JP3163127 and Yamanaka. It was further known that astaxanthin-containing lipids could be extracted from ruptured algae, as taught by Tanaka. One of ordinary skill in the art would have been motivated to combine these teachings to arrive at the claimed invention because JP3163127 and Tanaka both teach that astaxanthin extracted from green algae is desirable, and Tanaka teaches that such extraction is useful for the production of a commercial product. One would have had a reasonable expectation of success in combining these teachings because Tanaka teaches that the extraction

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process can be used with alga that have been cultivated by a variety of methods (p. 3, par. 23). It would therefore have been obvious to combine the teachings of the prior art to arrive at the claimed invention.

15. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

16. Applicant's arguments filed April 13, 2009 have been fully considered but they are not persuasive. Applicant argues that the claimed invention is not rendered obvious by the cited references because the references do not teach varying the AN/TN ration to ranges such as those recited in the claims, and that JP3163127 teaches away from lowering the AN/TN ratio to that recited in the instant claims. Applicant argues that the claimed invention is not rendered obvious by the prior art because JP3163127 and Yamanaka are not directed to the production of astaxanthin. Applicant also argues that the claimed process provides unexpected results and that one of ordinary skill in the art would not have combined the teachings of Yamanaka with those of JP3163127 because they are directed to the cultivation of different types of algae.

17. In response to applicant's argument that the claimed invention is not rendered obvious by the cited references because the references do not teach varying the AN/TN ration to ranges such as those recited in the claims, it is noted that the variation of organic and amino nitrogen sources are in fact taught by the references. Specifically, JP3163127 teaches that a variety of nitrogen sources may be used, and that these

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sources may be changed, and Yamanaka teaches that the carbon and nitrogen can be obtained from a variety of sources, such as those recited at col. 2, lines 62-68. One would therefore have recognized that nitrogen could have been derived for the cultivation of algae from a variety of sources, and would have been motivated to change these sources in the course of routine experimentation. Furthermore, although applicant argues that JP3163127 teaches away from the instant invention because it teaches that the AN/TN ratio should not be lowered, it is noted that the reference only teaches that amino acids may be preferential under certain conditions. This discussion of the alteration of nitrogen sources does not constitute a teaching away, as the reference makes clear that the algae will still grow with a variety of nitrogen sources.

18. In response to applicant's argument that the claimed invention is not rendered obvious by the prior art because JP3163127 and Yamanaka are not directed to the production of astaxanthin, it is noted that this element of the claimed process, which is recited in the dependent claims, is taught by Tanaka, who teaches a method of extracting a lipid containing astaxanthin from ruptured algae, specifically those of the genus *Haematococcus*. One of ordinary skill in the art would therefore have been motivated to grow algae of the genus for the production of astaxanthin, and would therefore have looked to JP3163127 for direction in methods for cultivating the organism, and further to Yamanaka for various algal cultivation techniques. Although applicant argues that Tanaka is not relevant to the lowering of the AN/TN ratios, this is not found to be persuasive because this teaching is provided in the other references, and the motivation to combine Tanaka with the teachings of the prior art to arrive at the

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claimed invention is discussed in detail in the above rejections. Also, although applicant claims that the JP3163127 and Yamanaka references would not have been combined for the enhanced production of astaxanthin, the motivation to combine the references for the enhanced cultivation of an algal strain has been provided in the rejections above. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

19. In response to applicant's argument that the claimed process provides unexpected results and that one of ordinary skill in the art would not have combined the teachings of Yamanaka with those of JP3163127 because they are directed to the cultivation of different types of algae, it is noted that, although applicant claims that the lowered AN/TN ratio would not have been desirable because it would have resulted in increased foaming, Yamanaka teaches that the use of various carbon and nitrogen sources, such as those that are derived from waste materials, can be advantageous. One would therefore have looked to alternate nitrogen sources in such a process, regardless of foaming, because they would have lowered production costs. Also, although Yamanaka is directed to the production of different types of algae, one would have been motivated to combine the teachings regarding the use of altered nitrogen sources with the teachings of JP3163127 because both references are directed to improving the nitrogen source in processes for the cultivation of algae. Applicant's arguments are therefore not found to be persuasive.

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20. Thus, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/

Primary Examiner, Art Unit 1651